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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 792-114 RCE III	
<p>Certificate of EFS-Web Transmission I hereby certify that this Fee(s) Transmittal is being transmitted to the U.S. Patent and Trademark Office via the Office's electronic filing system on the date indicated below</p> <p>on <u>January 11, 2011</u></p> <p>Signature <u>Shannon Farisch</u></p> <p>Typed or printed name <u>Shannon Farischon</u></p>		Application Number 10/696,845	Filed October 29, 2003
		First Named Inventor Stephen P. Mangin	
		Art Unit 3738	Examiner Christopher D. Prone
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>53,773</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mangin et al. Examiner: Prone, Christopher D.
Application No.: 10/696,845 Group Art Unit: 3738
Filed: October 29, 2003 Docket: 792-114 RCE III
Confirmation No: 9143 Dated: January 11, 2011
For: APPARATUS WITH VISUAL MARKER FOR GUIDING
DEPLOYMENT OF IMPLANTABLE PROSTHESIS

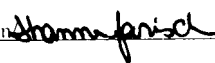
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Dated: January 11, 2011

Signature: Shannon Farischoff



STATEMENT IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In support of the concurrently-filed Notice of Appeal and Pre-Appeal Brief Request for Review, please consider the patentability of the claims of the above-identified application in view of the following remarks. As a petition for a three-month extension of time is being filed concurrently herewith, the Pre-Appeal Brief Request for Review and supporting statement are timely filed on January 11, 2011. A final Office Action was mailed on July 13, 2010, and an Advisory Action was mailed on October 15, 2010..

REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-11, 14-17, 23-25, 27-32, and 34-43 are pending in the application. Claims 1-4, 8-14, 23, 26-27, 30, 33 and 35-43 have been finally rejected. Claims 5-7, 15-17, 24-25, 28-29, 31-32, and 34 have been withdrawn from consideration. Claims 12-13, 18-22, 26, and 33 have been previously cancelled. Although claims 12, 26, and 33 have been previously cancelled, they have been improperly rejected. As the amendments which were presented in the Amendment and Response filed on October 13, 2010, were not entered by the Examiner, the claims which are

presently pending in the application are the claims as presented in the Amendment and Response which was filed on April 26, 2010.

The subject claimed invention relates to apparatuses for use by an operator in a cavity of a mammalian body. There are five independent claims, namely, claims 1, 23, 30, 39, and 43. Claims 1, 23, 30, and 39 all require, *inter alia*, a flexible elongate member, an expandable prosthesis, means for releasably securing the prosthesis to the distal extremity of the flexible elongate member, wherein the means for releasably securing the prosthesis includes a mesh, and a visual marker in the form of a colored band extending around the mesh. Claim 43 requires a flexible elongate member, means for releasably securing a prosthesis to the distal extremity of the flexible elongate member, and a visual marker which is colored to enhance visualization, which permits the placement of the prosthesis without the need of fluoroscopy, and which is capable of being freed from the prosthesis.

A. Rejection under 35 U.S.C. §103 in view of Strecker and Chevalier

Claims 1-4, 8, 12-14, 23, 26, 27, 30, 33, 35, and 39-43 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over U.S. Patent No. 5,653,748 to Strecker (hereinafter “Strecker”) in view of U.S. Patent No. 5,401,257 to Chevalier Jr. et al. (hereinafter “Chevalier”). The Examiner has stated that “Strecker fails to disclose a visual marker comprising a colored loop extending around the prosthesis that is a different color than the releasing means.” (Final Office Action dated July 13, 2010, page 2). Nevertheless, the Examiner has alleged that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the marker bands with colorant of Chevalier with the delivery device of Strecker in order to enhance the trackability of the implant.” (Final Office Action dated July 13, 2010, page 3). Applicants respectfully traverse.

Strecker nowhere discloses a colored band which extends around mesh as required by independent claims 1, 23, 30, and 39, and Chevalier fails to cure Strecker’s deficiencies. Rather, Chevalier uses a laser to create markings on a stent which is made of a polymer (such as ethylvinyl acetate). (See column 8, lines 4-32, of Chevalier). Specifically, Chevalier discloses that its “markings, as well as others that indicate the size, length and manufacturer of the stent, can be placed on the stent using a laser scribing system” and that “[t]he markings are also

relieved into the surface of the tube.” (Chevalier, column 7, lines 58-61, and column 8, lines 17-28). Thus, Strecker and Chevalier fail to disclose or suggest apparatuses as recited in independent claims 1, 23, 30, 39 which include a visual marker in the form of a colored band which extends around mesh.

Strecker and Chevalier also fail to disclose or suggest an apparatus having a visual marker which is capable of being freed from the prosthesis, as recited in claim 43. Rather, Chevalier explicitly discloses that its “markings are retained even after the stent has been within the body for an extended period of time.” (Chevalier, column 8, lines 35-37).

Moreover, it is respectfully submitted that one of ordinary skill in the art would not apply the laser scribing system of Chevalier (which is intended to be retained on a stent for an extended period of time) to the mesh of Strecker (which is pulled off to allow the prosthesis of Strecker to reach its “intended expansion position”). (*See, e.g.*, column 2, lines 4-12, of Strecker). Certainly, no showing has been made that such a modification could be made with any predictability of results, let alone with a reasonable expectation of success.

As stated by the Examiner on page 2 of the Final Office Action dated July 13, 2010, the mesh of Strecker is formed from a crocheted material (14) including a thread having a plurality of loops. As such, the mesh of Strecker is not a tube formed from a polymer, as specifically disclosed in Chevalier (*see* column 8, lines 8-32, of Chevalier). Indeed, as the laser of Chevalier “burns, oxidizes or otherwise removes the tubing polymer” (*see* column 8, lines 22-23, of Chevalier), one of ordinary skill in the art would expect it to burn or otherwise remove the thread of Strecker, thereby rendering the thread unsuitable for its intended use as a mesh which can be pulled off of the prosthesis of Strecker to allow the prosthesis to expand. *See* MPEP §2143.01.V (“If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.”) (internal citation omitted). Thus, Applicants respectfully submit that one of ordinary skill in the art would not make the modification proposed by the examiner, let alone have a reasonable expectation of success with respect to arriving at apparatuses as recited in independent claims 1, 23, 30, 39, and 43.

Applicants respectfully submit that it appears that it is only through hindsight reconstruction using Applicants’ disclosure as a blueprint that the Examiner attempts to reach the

present invention based on the disclosures of Strecker and Chevalier. Hindsight reconstruction using only Applicants' disclosure to arrive at the present invention is, however, strictly prohibited. *See* M.P.E.P. § 2145.X.A.; *see also KSR International Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1397 (2007) (internal citations omitted) (“[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”). Moreover, it is respectfully submitted that disclosures from each of Strecker and Chevalier are being selectively chosen and taken out of context without regard to what those references disclose in their entirety or without regard to what they fairly teach or suggest. It is impermissible, however, to pick and choose from a reference only so much that supports the alleged rejection, while ignoring their teachings as a whole. *See, e.g., In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (noting that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention”); *see also* M.P.E.P. §2145.X.A. Significantly, impermissible hindsight cannot be used to support a rejection.

Thus, Applicants respectfully submit that independent claims 1, 23, 30, 39, and 43, and dependent claims 2-4, 8-11, 14, 27, 35, and 40-42, are not obvious in view of Strecker and Chevalier. Indeed, there is no disclosure or suggestion in Strecker and Chevalier of the subject matter of dependent claims 2-4, 8-11, 14, 27, 35, and 40-42. Claims 12, 26, and 33 have been cancelled, rendering the rejection improper with respect to those claims.

Reconsideration and withdrawal of the rejection of claims 1-4, 8, 12-14, 23, 26-27, 30, 33, 35, and 39-43 are respectfully requested.

B. Rejection under 35 U.S.C. §103 in view of Strecker, Chevalier, and Ravenscroft

Claims 9-11 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over Strecker as modified by Chevalier in view of U.S. Patent No. 5,480,423 to Ravenscroft (hereinafter “Ravenscroft”). The Examiner has cited Ravenscroft merely for a disclosure of “a length shortening self-expanding stent.” (Final Office Action, page 3). Applicants respectfully traverse.

As discussed above, Strecker and Chevalier fail to render claim 1 obvious. Claims 9-11 all depend either directly or indirectly from claim 1 and thus are not obvious over Strecker and

Chevalier for at least the same reasons discussed with respect to claim 1. Moreover, Ravenscroft fails to overcome the deficiencies of Strecker and Chevalier. Indeed, there is no disclosure or suggestion in Strecker, Chevalier, and Ravenscroft of the subject matter of claims 9-11.

Reconsideration and withdrawal of the rejection of claims 9-11 is respectfully requested.

C. Rejection under 35 U.S.C. §103 in view of Strecker, Chevalier, and Fischell

Claims 36-38 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over Strecker as modified by Chevalier in view of U.S. Patent No. 5,792,144 to Fischell et al. (hereinafter "Fischell"). The Examiner has cited Fischell merely for the disclosure of a stent-delivery catheter including bands of a radiopaque metal coated in silicone. (Final Office Action, page 4). Applicants respectfully traverse.

As discussed above, Strecker and Chevalier fail to render claims 1, 23, and 30 obvious. Claim 36 depends from claim 1, claim 37 depends from claim 23, and claim 38 depends from claim 30. Thus, claims 36-38 are not obvious over Strecker and Chevalier for at least the same reasons discussed above with respect to independent claims 1, 23, and 30, respectively. Moreover, Fischell fails to overcome the deficiencies of Strecker and Chevalier. Indeed, there is no disclosure or suggestion in Strecker, Chavalier and Ravenscroft of the subject matter of claims 36-38.

Reconsideration and withdrawal of the rejection of claims 36-38 is respectfully requested.

Concluding Remarks

Favorable action is earnestly solicited. If there are any questions, the Examiner is respectfully requested to contact the undersigned at the number listed below.

Respectfully submitted,



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